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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JEROME ASIUS, HATEM FESSI, FRANCK GOUCHET,
BENEDIC TE LEGLENNE and ELISABETH LAUGHIER-LAGLENNE

Appeal 2009-003445
Application 10/809,349
Technology Center 3700

Oral Hearing Held: September 15, 2009

Before WILLIAM F. PATE, III, STEFAN STAICOVICI and KEN B. BARRETT, *Administrative Patent Judges.*

ON BEHALF OF THE APPELLANT:

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The above-entitled matter came on for hearing on Wednesday, September 15, 2009, commencing at 10:20 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Christine L. Loeser, Notary Public.

PROCEEDINGS

JUDGE PATE: I would like you to introduce your guest.

MR. AMERNICK: With me is Ronald Borg, who is also a registered patent attorney who is an in-house counsel for Sanofi-Aventis, who happens to be the Assignee of this Application.

JUDGE PATE: We have had a chance to look at this case beforehand so we think we are up to speed on the technology and we would like to hear your arguments about patentability.

MR. AMERNICK: Okay. That's fine. As you are aware, the question relates to whether or not the claimed invention is obvious or nonobvious.

Two references are relied upon for most of the claims. The primary reference is a Sander patent. That's US patent 5,356,629, and then a patent to Supersaxo, US patent 5,470852, which the Examiner relied upon for disclosure related to freeze-drying.

With respect to Sander, the primary reference, first of all, as clear from the Examiner's position, Sander does not disclose freeze drying. We point out that Sanders does not disclose a reconstitutable product that would form a hydrogel. Sander does not disclose a hydrogel, and Sander is not concerned with an injectable composition and does not specifically require microparticles.

All of these aspects of the present invention are very important for achieving the reconstitutable product that will provide an injectable composition that's used, and if you obviously saw through the specification for reparative plastic surgery used for injection into soft tissue.

Just to drop back one moment, this invention actually has resulted in a commercial product. The commercial product is certainly out by Sanofi-Aventis. It is under the name Sculptra and it was initially approved for treating for AIDS patients to replace fat facial tissue.

Now most recently, it has been approved for more generalized use and it has been used in Europe since about 2002.

Sander, getting back to Sander, relates to a moldable composition. All of the examples, all of the specific disclosure in Sander relates to a putty that can be implanted into, say, a surgical site or a wound site and then it's shaped or molded to a repair bone or large bone defect by using a surgical spatula.

So nowhere -- and how Sander gets to that, they have a matrix and a biocompatible material. That biocompatible material can either be bioresorbable or it can be a non-bioresorbable material.

To begin with, the putties disclosed in Sander are not gels. One of the definitions and the more usual definition of gel we presented in Exhibit 1 from Hawley's Condensed Chemical Dictionary and, basically, it is a colloidal dispersion that provides a jelly-like consistency or structure.

The putties are not that and, in fact, in the parent patent, this is a revision of a prior application which was subsequently issued as a patent. There was extensive prosecution in that case and on somewhat similar issues, the Office did conclude that a putty was not the same thing as the definition of a gel and, of course, we are also talking about not just a gel but hydrogel and an injectable hydrogel.

JUDGE PATE: The Examiner points to column 2 in Sander where he says it is a semi-solid material and it says it could be a gel, paste, putty or clay.

MR. AMERNICK: What he talks about there, if we read that whole portion is that they are talking about the consistency of it, the flowability of it, but not necessarily all the other characteristics that come into play because they talk about it being, like you stated, a semi-solid, possessing the qualities of both a solid and a liquid, a highly viscous substance, but yet flowable to some extent such as gel, paste, putty or clay, which is capable of being molded or shaped.

So what they are really talking about is that one characteristic, that one property and certainly gels can have, as far as the viscosity aspect or flowability aspect, certainly can fill that particular requirement, but the other characteristics of a gel are not really referred to or related there.
In fact, if you are looking at that whole sentence or even talking about clay, obviously Sander is not making a clay but they are looking for, again, something with the viscosity characteristics of a clay, paste, gel or putty, so they are kind of broadening that out.

So I don't think they are really talking about forming a gel or, more specifically, a hydrogel there.

JUDGE PATE: With the substances here disclosed, you could make a gel.

MR. AMERNICK: If you were able to select the specific materials and, again, I know the Examiner pointed to the fact that they do disclose cellulosic ethers but recognize, and this is pretty well known, that the cellulosic ethers are inclusive of a very large, huge range of compounds and

materials that might have a similar chemical name to them but differ vastly or can differ vastly with respect to many, many other properties of the ether, such as molecular weight, degree of cross-linking, solubility characteristics, viscosity characteristics, have they been -- has the cellulosic ether been substituted with something such as sodium.

All those things will dictate what types of characteristics it has, and just generally stating it, it is a little less than stating something as in, quote, a polymer, but in any event, it does include a vast, vast range of materials. And I think more instructively, you should go back, look at the examples, and it's constantly speaking about putty, putty, putty, constantly speaking about something that has to be shapeable, moldable, with a surgical spatula. We are looking at something that is reconstitutable to become an injectable. Again, with respect to an injectable, I'm not quite certain why one would go or even whether you would go to an injectable when you are talking about an implant that you are going to shape to or mold to a bone defect.

Also, with respect to the freeze-drying aspect, again, looking at Sander, I don't think there would be, one, any reason to carry out any freeze-drying when you look at the method process by which Sander puts together their composition. They take the two powder materials which are the matrix and the biocompatible material, mix them together.

Again, they are in powdered, dry form, in order to get a uniform dispersion of the biocompatible material in the matrix and then right before use, they will add some type of fluid to get the type of consistency needed to achieve the putty and, again, to make it moldable and shapeable with the spatula.

Also, if you take a putty, for example, and even at that state, if you would freeze-dry it, basically you would probably form some type of lumpy material. You are not going to be able to then add back, say, a liquid, water, for example, and obtain a hydrogel.

To get a hydrogel, you are going to have to start with the hydrogel, then carry out the steps or stages of, say, the process of the drying, in this case, the freeze-drying and then when you add back the water, you go back to its more or less original stage or original state there.

And again, we feel that hydrogels are not inherent for the reasons we just spoke about.

Also, our claims require that we look at microparticles. The particle range in Sander is an extremely broad range. The preferred particles are much larger than microparticles and there is mention of particles which could be in the micron sizes but they are kind of as an afterthought.

And the size does not seem to be important anyway in Sander because of the fact, again, that they are dealing with something that's an implant, that's put in during a surgical procedure, not something that's injectable where something to be injectable, the particle size does become an important characteristic of the composition.

Unless you have any other questions ...

JUDGE PATE: Any questions, Judge Barrett?

JUDGE BARRETT: No.

JUDGE PATE: Judge Staicovici?

I have no more questions. We will take this case under advisement. Thank you very much.

MR. AMERNICK: We thank you for your time.

(Whereupon, the proceeds, at 10:32, were concluded.)